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SIDBERRY, H	
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DATE MAILED: 03/17/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on 2/17/95 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474..
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 2-5, 7-10, 19-54, 62-64 are pending in the application.
   Of the above, claims 2-5, 7-10, 20-46, 47-58, 61 are withdrawn from consideration.
2. ☒ Claims 12, 11-18, 55-60 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 19, 62-64 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

326 (Rev. 2/83)

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

After further consideration the finality of the last Office Action is withdrawn.

Claims 55-58, 59, 60 have been cancelled. Claims 2-5, 7-10, 20-52, 61 have been withdrawn from consideration. Claims 53-58 submitted 4/4/94 depend from claims 47-52 and were also withdrawn form consideration. Claims 1, 6, 11-18, 59, 60 were cancelled.

Claims 19 and 62 and new claims 63-64 are under examination.

The rejection of claim 19 and 62 under 35 U.S.C. § 102(b) as being anticipated by Gupta et al is withdrawn, in view of the limitation directed to a purity level.

The rejection of claim 19 under 35 U.S.C. § 112, second paragraph, as being indefinite is obviated by the amendment to the claims.

The objection to the specification and the rejection of claim 19 under 35 U.S.C. § 112, first paragraph is maintained.

The specification does not, in fact, demonstrate that administration of UTAA will result in enhancement of antibody to UTAA or any subunit of UTAA. Nor does the specification enable the administration of UTAA, for the purpose of preventing or treating cancer.

The rejection of claims 19, now claims 63, 64 under 35 U.S.C. § 102(b) as being anticipated by Real et al US Patent 4 562 160 is maintained.

Applicants contend the UTAA has a molecular weight of 590-620 kd, however, the claim is directed to an "antigen composition" which after SDS-PAGE shows a 90-100 kd molecular weight. Thus, the composition once resolved on a SDS-PAGE shows a band at 90-100 kd. Real et al 90 kd antigen is resolved from a composition of concentrated culture medium, however Real et al does not indicate the molecular weight of the starting composition, but indicates that a 10 kd molecular weight cutoff was used when concentrating the antigen. Similarly, Applicants antigen was derived from culture medium which was concentrated with a 10 kd molecular weight cutoff. We can therefore make no determination of the molecular

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weight of the Real et al starting material, but only that of the resultant precipitated antigen which is within the molecular weight range claimed.

Applicants' also contend that the FD antigen of Real et al is 90 kd under non-reduced conditions. Examination of Real et al shows that both reducing and non-reducing conditions. Real et al indicates that the component which was precipitated by FD serum from the cells was 90 kd, but does not state the gel conditions. The referenced col 4,line 59, col 5,line 8 does not indicate that the 90 kd was PAGE resolved "unreduced" or reduced.

Regarding the issue of prevalence on melanoma cells. It is unclear how Applicant derived the <3% on melanoma cells for the FD antigen. Further, the claims do not include any limitations directed to prevalance of the antigen. As Real et al did not assay to determine the "prevalance" of the FD antigen, no determination can be made.

Applicant further states that the Examiner's statements regarding the pI are without scientific support.

The Examiner submits Dunbar et al (Guide to Protein Purifiction, Methods of Enzymology, pages 442-443) who indicates in "2D-PAGE can be used for the estimation of the relative isolectric points and molecular wieghts of proteins. However, it is generally inadequate to use this as the sole method for the precise determiantion of these parameters. For example, the disulfide bonds of the proteins analyzed by 2D-PAGE are usually reduced so the protein patteerns may reflect subunit peptides. The pI and molecular weight values observed may therefore be different from those of the native proteins. One should be careful not to overinterpret data obtained from electrofocusing and 2D-PAGE." (see pages 442, Applications of 2D-PAGE continuing to top of page 443)

The pI referenced by Real et al is directed to the subunit precipitated by the serum. Real et al does not indicate the pI of the starting composition. Applicant also does not indicate the pI of the resultant 90-100 kd subunit. The fact that the pI is different for the precipitated protein of Real et al, does not

establish that it is different from that claimed, because the pI of 6.1 is for the 590-620 kd starting composition, not the 90-100 kd recited in the claims.

In summary, Applicants statements have not served to resolve that Real et al 90 kd antigen is not the same as that claimed.

The following are new grounds of rejection.

The disclosure is objected to because of the following informalities: This application does not contain an Abstract of the Disclosure as required by 37 C.F.R. 1.72(b). An Abstract on a separate sheet is required. Appropriate correction is required.

Claim 19 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is vague and confusing as drafted. It is unclear what Applicant is claiming as inducing and enhancing are not equivalent terms.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless--

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this country or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 62-64 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Euhus et al or Paulie et al.

The claims are directed to an antigen composition comprising a tumor antigen, which is UTAA, and after SDS-PAGE the antigen show a molecular weight of 90-100 kd.

Euhus et al (Proceedings of ASCO March 1988, Abstract 169) disclose an antigen composition of molecular weight 620 kd, identified as UTAA, which after SDS-PAGE exhibited a molecular weight of 111 kd, corresponding to UTAA in urine. (see the Abstract)

Paulie et al (Cancer Immunology Immunotherapy 17:173-179, 1984) disclose a 92 kd antigen associated with bladder carcinoma which was immunoprecipitated from solubilized carcinoma cells. (see Abstract, page 173, page 175, figure 1 and lft side.)

The specification indicates that the molecular weight of UTAA is 520 kd-620 kd, and the UTAA subunit is 90 kd from serum and 100 kd from urine.

The prior art antigen compositions appear to be the same as that claimed, because of the disclosed molecular weight of the antigen composition, (Euhus et al) and after SDS-PAGE results a subunit antigen within the molecular weight range claimed (Paulie et al).

Given the variability in protein and glycoprotein molecular

wieghts when determined by different methods, especially for glycoproteins, the proteins of Euhus et al and Paulie et al, at 111 kd and 92 kd respectively, appear to be consistent with the claimed range of about 90-100 kd.

Therefore, the prior art antigen compositions and resultant subunit appear to be consistent with that claimed with other identifying characteristics inherent.

And if the prior art antigen compositions are not the same as that claimed, it is an obvious variation of that claimed, which the teachings of the prior art reference(s) would have reasonably suggested to one of ordinary skill in the art at the time the invention was made, the isolation and further characterization of UTAA antigens, making the claimed invention as a whole prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made.

Since the Patent Office does not have the facilities for examining and comparing Applicants' antigen composition with that of the prior art, the burden is on Applicant to show and unobvious difference between the claimed composition and the composition of the prior art (i.e., that the antigen of the prior art does not posses the same material structural and functional characteristics of the claimed antigen) See In re Best, 195 USPQ 430, 433 (CCPA 1977).

Claim 19 is rejected under 35 U.S.C. § 103 as being unpatentable over Euhus et al.

The claim is directed to a method for inducing antibody to UTAA by giving the antigen.

Euhus et al disclose the UTAA antigen and indicate that a MAB to the antigen has been developed.

The prior art differs from that claimed, in not specifically disclosing "administration of the UTAA antigen".

Methods of making monoclonal antibody are known in the art and given the availability of the UTAA antigen, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further "administer" UTAA for the purpose to obtaining a source of antibody which would be useful in assay, such

as ELISA, to detect the UTAA in serum samples or "provide reagents for the immunoprognosis of human melanoma".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to H. Sidberry whose telephone number is (703) 308-0170.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to the Group 1800 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 fax Center number is (7030 305-7939)

Sidberry/hfs
March 17, 1995

HAZEL F. SIDBERRY
PRIMARY EXAMINER
GROUP 1800